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7 June 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/01218 A3

(54) Title: METHODS FOR OBTAINING AND USING HAPLOTYPE DATA

(57) Abstract: Methods, computer program(s) and database(s) to analyze and make use of gene haplotype information. These include methods, program, and database to find and measure the frequency of haplotypes in the general population; methods, program, and database to find correlation's between an individual's haplotypes or genotypes and a clinical outcome; methods, program, and database to predict an individual's haplotypes from the individual's genotype for a gene; and methods, program, and database to predict an individual's clinical response to a treatment based on the individual's genotype or haplotype.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/17540

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :G06F 7/00, 17/00; G01N 33/48, 33/50; G06T 1/00
US CL :345/418, 961; 702/19, 20; 707/100, 102, 104
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 345/418, 961; 702/19, 20; 707/100, 102, 104

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,874,256 A (BERTINA ET AL) 23 February 1999 (23-02-99), see in particular abstract and claims.	1-21,30-33, 35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 14 NOVEMBER 2000	Date of mailing of the international search report 23 FEB 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Dorothea Lawrence for MARIANNE P. ALLEN Telephone No. (703) 308-0196

Form PCT/ISA/210 (second sheet) (July 1998)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/17540

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,773,220 A (DEKOSKY ET AL) 30 June 1998 (30-06-98), see in particular abstract and claims.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y,P	US 5,972,614 A (RUANO ET AL) 26 October 1999 (26-10-99), see in particular abstract; claims; column 6, lines 33-55; column 12, lines 10-25.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160, 171-183
Y, P	US 6,022,683 A (POIRIER) 08 February 2000 (08-02-00), see in particular abstract and claims.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160, 171-183
Y, P	US 6,043,040 A (ACTON) 28 March 2000 (28-03-00), see in particular abstract, claims, and columns 49-59.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135, 137,145-153,155-160,171-183
Y	US 5,648,482 A (MEYER) 15 July 1997 (15-07-97), see in particular abstract, claims, and columns 23-26.	1-21,30-33,35,43-51,53-58,69-78,8384,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y, P	US 6,030,778 A (ACTON ET AL) 29 February 2000 (29-02-00), see in particular abstract, claims, and columns 25-30.	1-21,30-33, 35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/17540

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	KLEYN et al. Genetic Variation as a Guide to Drug Development. Science. 18 September 1998, Vol. 281, pages 1820-1821, see entire document.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y	MORI et al. HLA Gene and Haplotype Frequencies in the North American Population. Transplantation. 15 October 1997, Vol. 64, No. 7, pages 1017-1027, see entire document.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y	MORI et al. Computer program to predict likelihood of finding an HLA-matched donor: Methodology, validation, and application. Biology of Blood and Marrow Transplantation. October 1996, Vol. 2, pages 134-144, see entire document.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y	MATISE, T. C. Genome Scanning for Complex Disease Genes Using the Transmission/Disequilibrium Test and Haplotype-based Haplotype Relative Risk. Genetic Epidemiology. 1995, Vol. 12, No. 6, pages 641-645, see entire document.	121,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y	COOPER et al. Network Analysis of Human Y Microsatellite Haplotypes. Human Molecular Genetics. 1996, Vol. 5, No. 11, pages 1759-1766, see entire document.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y	GENE et al. Haplotype frequencies of eight Y-chromosome STR loci in Barcelona (North-East Spain). International Journal of Legal Medicine. 1999, Vol. 112, pages 403-405, see entire document.	1-21,30-33,3543,-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/17540

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CLARK et al. Haplotype Structure and Population Genetic Inferences from Nucleotide-Sequence Variation in Human Lipoprotein Lipase. American Journal of Human Genetics. 1998, Vol. 63, pages 595-912, see entire document.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y	CASHMAN et al. The Irish cystic fibrosis database. Journal of Medical Genetics. 1995, Vol. 32, No. 12, pages 972-975, see entire document.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y, P	TISHKOFF et al. The Accuracy of Statistical Methods for Estimation of Haplotype Frequencies: An Example from the CD4 Locus. American Journal of Human Genetics. August 2000, Vol. 67, No. 2, pages 518-522, see entire document.	1-21,30-33,35,43-51,53-5869-78, 83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y	PERLIN et al. Toward Fully Automated Genotyping: Allele Assignment, Pedigree Construction, Phase Determination, and Recombination Detection in Duchenne Muscular Dystrophy. American Journal of Human Genetics. 1994, Vol. 55, No.4, pages 777-787, see entire document.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183
Y	HOANG et al. PAH Mutation Analysis Consortium Database: A Database for Disease-producing and Other Allelic Variation at the Human PAH Locus. Nucleic Acids Research. 1996, Vol. 24, No. 1, pages 127-131, see entire document.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160, 171-183
Y, P	STEPHENS et al. Single-nucleotide Polymorphisms, Haplotypes, and Their Relevance to Pharmacogenetics. Molecular Diagnosis. December 1999, Vol. 4, No. 4, pages 309-317, see entire document.	1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160, 171-183

INTERNATIONAL SEARCH REPORT

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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
1-21,30-33,35,43-51,53-58,69-78,83-84,86,94-102,104-109,120-129,134-135,137,145-153,155-160,171-183

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☒ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

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B. FIELDS SEARCHED
Electronic data bases consulted (Name of data base and where practicable terms used):

DIALOG (files 5, 155) and EAST (files U.S. Patents, European abstracts, Japanese abstracts, and Derwent) search terms: pharmacogenomic, pharmacogenetic, haplotype, genotype, database, computer, clinical trial, population genetics, polymorphism, SNP, Hardy-Weinberg, Mendelian, linkage, phylogenetic, pedigree, locus, gene, phased, unphased

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING
This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s)1-8, 69-72, and 120-124, drawn to a method of generating a haplotype database, computer-usable medium, and computer programmed therefore.
Group II, claim(s) 9-12 and 73, drawn to a method of predicting the presence of a haplotype and computer-usable medium therefore.
Group III, claim(s) 13-21, 74-78, and 125-129, drawn to a method of identifying correlation between haplotype pair and clinical response, computer-usable medium, and computer programmed therefore.
Group IV, claim(s) 22-29, 79-82, 130-133, drawn to a method for determining susceptibility to a condition/disease, computer-usable medium, and computer programmed therefore.
Group V, claim(s) 30-33, 83-84, and 134-135, drawn to a method for predicting response to treatment, computer-usable medium, and computer programmed therefore.
Group VI, claim(s) 34, 85, and 136, drawn to a method for generating a tree structure, computer-usable medium, and computer programmed therefore.
Group VII, claim(s) 35, 86, and 137, drawn to a method for displaying haplotype pair frequency, computer-usable medium, and computer programmed therefore.
Group VIII, claim(s) 36-37, 87-88, and 138-139, drawn to a method for displaying a linkage screen, computer-usable medium, and computer programmed therefore.
Group IX, claim(s) 38-40, 89-91, and 140-142, drawn to a method for displaying a phylogenetic tree screen, computer-usable medium, and computer programmed therefore.
Group X, claim(s) 41-42, 92-93, and 143-144, drawn to a method for displaying genotypic analysis, computer-usable medium, and computer programmed therefore.
Group XI, claim(s) 43-51, 94-102, and 145-153, drawn to a method to displaying clinical response values, computer-usable medium, and computer programmed therefore.
Group XII, claim(s) 52, 103, and 154, drawn to a method for carrying out a genetic algorithm, computer-usable medium, and computer programmed therefore.
Group XIII, claim(s) 53, 104, and 155, drawn to a method for displaying correlations, computer-usable medium, and computer programmed therefore.
Group XIV, claim(s) 54-55, 105-106, and 156-157, drawn to a method for conducting a clinical trial, computer-usable medium, and computer programmed therefore.
Group XV, claim(s) 56-58, 107-109, and 158-160, drawn to a method for inferring genotype, computer-usable medium, and computer programmed therefore.
Group XVI, claim(s) 59-68, 110-119, and 161-170, drawn to a method of determining polymorphic sites or subhaplotypes, computer-usable medium, and computer programmed therefore.
Group XVII, claim(s) 171-175 and 183, drawn to a data structure.
Group XVIII, claim(s) 176-182, drawn to a method for storing and organizing biological information.

The inventions listed as Groups I-XVIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of each method is the starting materials, method steps, and goal of each method. The corresponding computer-usable medium and computer programmed therefore form part of the inventive concept with each method. Note that PCT Rule 13 does not provide for multiple methods or products.

Label	Chr	EGD	010628c08c00_3B	010628c08c15_3B	010628c08c16_3B	010628c08c17_3B	010628c08c19_3B	010628c08c23_3B	010628c08c24_3B	010628c08c27_3B	010628c08c39_3B
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WIAF-2225	17	5.43	B	No Signal	No Signal	No Signal	No Signal	No Signal	B	No Signal	No Signal
WIAF-39	17	16.71	A	A	No Signal	No Signal	A	No Signal	A	A	A
WIAF-918	17	16.71	No Signal	A	No Signal	No Signal	No Signal	No Signal	A	No Signal	No Signal
WIAF-747	17	28.31	A	A	A	A	No Signal	No Signal	A	A	A
WIAF-748	17	28.31	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	B	AB_B	AB_B
WIAF-2541	17	40.6	No Signal	B	B	No Signal	B	B	B	B	B
WIAF-2293	17	61.75	B	B	B	B	B	No Signal	B	B	B
WIAF-3030	17	62.74	A	A	A	A	A	No Signal	A	A	A
WIAF-422	17	66.81	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal
WIAF-1741	17	68.16	A	A	A	A	A	No Signal	A	A	A
WIAF-1021	17	74.8	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal
WIAF-3779	17	74.92	B	B	B	B	B	No Signal	B	B	B
WIAF-3780	17	74.92	A	A	A	A	A	No Signal	A	A	A
WIAF-1652	17	75.52	B	B	B	B	B	No Signal	B	B	B
WIAF-507	17	75.52	A	A	A	A	A	No Signal	A	No Signal	A
WIAF-2874	17	79.17	B	B	B	B	No Signal	No Signal	B	B	B
WIAF-1325	17	91.44	No Signal	B	B	B	No Signal	B	B	B	B
WIAF-2760	17	101.55	A	A	A	No Signal	A	A	A	No Signal	A
WIAF-2560	**17**	**105.31**	**AB**	**No Signal**	**A**	**No Signal**	**No Signal**	**A**	**No Signal**	**No Signal**	**A**
WIAF-2450	17	112.28	B	B	B	B	B	B	B	B	B
WIAF-2413	17	116.33	A	A	A	A	A	A	A	A	A
WIAF-2858	**17**	**116.33**	**AB**	**B**	**A**	**A**	**B**	**A**	**B**	**A**	**A**
WIAF-3305	17	122.68	No Signal	B	B	B	B	No Signal	B	B	No Signal
WIAF-1133	17		B	B	B	B	No Signal	No Signal	B	B	B
WIAF-1134	17		No Signal	A	A	A	No Signal	No Signal	No Signal	No Signal	No Signal
WIAF-1138	**17**		**AB**	**A**	**B**	**B**	**No Signal**	**B**	**A**	**B**	**B**
WIAF-1164	17		B	B	B	B	No Signal	No Signal	B	B	B
WIAF-1274	17		A	A	A	No Signal	No Signal	No Signal	A	A	A
WIAF-1519	17		No Signal	No Signal	No Signal	B	No Signal	No Signal	No Signal	No Signal	B
WIAF-1996	17		A	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal
WIAF-2145	17		A	A	A	A	A	No Signal	A	A	A
WIAF-2375	17		No Signal	A	A	No Signal	No Signal	A	A	A	A
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WIAF-2407	17		No Signal	B	No Signal	No Signal	B	No Signal	B	No Signal	No Signal
WIAF-2445	17		A	A	A	A	A	A	A	A	A
WIAF-2573	**17**		**AB**	**B**	**A**	**AB_A**	**No Signal**	**No Signal**	**B**	**A**	**A**
WIAF-2876	**17**		**AB**	**B**	**No Signal**	**No Signal**	**No Signal**	**A**	**No Signal**	**No Signal**	**A**
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WIAF-3051	17		B	B	B	B	B	No Signal	B	B	B
WIAF-3197	17		A	A	A	No Signal	No Signal	No Signal	A	A	A
WIAF-3236	17		B	B	No Signal	AB	No Signal	B	No Signal	B	B
WIAF-3660	17		A	A	No Signal	No Signal	No Signal	No Signal	A	A	A
WIAF-3889	17		A	A	A	No Signal	No Signal	No Signal	A	A	A
WIAF-4164	**17**		**AB**	**AB**	**A**	**A**	**B**	**B**	**B**	**A**	**A**
WIAF-423	17		B	B	B	B	No Signal	No Signal	B	B	B
WIAF-4554	**17**		**AB_A**	**B**	**A**	**A**	**B**	**B**	**B**	**A**	**AB_A**
WIAF-4585	17		A	A	No Signal	No Signal	No Signal	No Signal	A	A	A
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WIAF-752	17		A	A	A	No Signal	No Signal	No Signal	A	No Signal	A
WIAF-821	**17**		**No Signal**	**A**	**No Signal**	**No Signal**	**No Signal**	**No Signal**	**A**	**B**	**B**
WIAF-908	**17**		**AB**	**AB**	**A**	**A**	**B**	**No Signal**	**B**	**A**	**A**
WIAF-963	**17**		**No Signal**	**No Signal**	**No Signal**	**No Signal**	**No Signal**	**No Signal**	**No Signal**	**No Signal**	**No Signal**

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No Signal	No Signal	No Signal	No Signal	B	No Signal	B	No Signal
No Signal	No Signal	A	A	A	No Signal	No Signal	No Signal
No Signal	No Signal	No Signal	A	No Signal	No Signal	No Signal	No Signal
No Signal	A	No Signal	A	No Signal	No Signal	A	A
No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	B
B	B	No Signal	B	B	AB_B	B	B
No Signal	B	B	B	B	B	B	B
No Signal	A	A	A	A	A	A	A
No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	A	A
No Signal	A	A	A	A	A	A	A
No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	A	A
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No Signal	A	A	A	A	A	A	A
No Signal	B	B	B	B	B	B	B
No Signal	A	A	A	A	A	A	A
No Signal	No Signal	B	B	B	B	B	B
B	No Signal	No Signal	No Signal	B	B	B	No Signal
A	A	A	A	A	A	A	A
No Signal	**AB**	**No Signal**	**No Signal**	**B**	**B**	**AB**	**AB**
B	B	B	B	B	B	B	B
A	A	A	A	A	A	A	A
B	**B**	**B**	**B**	**B**	**AB**	**AB**	**AB**
No Signal	No Signal	B	No Signal	B	B	No Signal	No Signal
No Signal	B	B	B	B	B	B	B
No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	A	No Signal
A	**No Signal**	**No Signal**	**A**	**A**	**A**	**AB**	**AB**
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No Signal	A	No Signal	A	No Signal	A	A	A
No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	B	B
No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	A	A
No Signal	A	A	A	A	A	A	A
No Signal	No Signal	No Signal	A	No Signal	A	A	A
A	A	A	A	A	A	A	A
B	B	B	B	B	B	B	B
A	A	A	A	A	A	A	A
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No Signal	**No Signal**	**A**	**No Signal**	**No Signal**	**No Signal**	**AB**	**AB**
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No Signal	No Signal	B	B	B	B	B	B
No Signal	A	No Signal	A	No Signal	No Signal	A	A
No Signal	No Signal	B	No Signal	No Signal	No Signal	B	B
A	A	No Signal	A	A	No Signal	A	A
No Signal	A	No Signal	A	No Signal	No Signal	A	A
No Signal	**B**	**B**	**B**	**B**	**AB**	**AB**	**AB**
No Signal	No Signal	B	B	B	B	B	B
B	**B**	**B**	**B**	**B**	**AB**	**No Signal**	**AB**
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No Signal	No Signal	No Signal	No Signal	No Signal	No Signal	A	No Signal
No Signal	No Signal	A	A	A	No Signal	A	A
A	**B**	**No Signal**	**A**	**B**	**No Signal**	**AB**	**AB**
No Signal	**A**	**B**	**B**	**B**	**AB**	**AB**	**AB**
No Signal	**No Signal**	**No Signal**	**No Signal**	**No Signal**	**No Signal**	**AB**	**AB**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/17994

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68; C12P 19/34; C07H 21/02, 21/04
US CL : 435/6, 91.2; 536/23.1, 23.5, 24.31, 24.33

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 435/6, 91.2; 536/23.1, 23.5, 24.31, 24.33

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	BAUMER et al. Screening for UBE3A gene mutations in a group of Angelman syndrome patients selected according to non-stringent criteria. Human Genetics. 1999, Vol. 105, pages 598-602, especially pages 599-600.	1and 2
X	KISHINO et al. Genomic organization of the UBE3A/E6-AP gene and related pseudogenes. Genomics. 1998, Vol. 47, pages 101-107, especially pages 101-102.	1 and 2
X	MALZAC et al. Mutation analysis of UBE3A in Angelman syndrome patients. American Journal of Human Genetics. 1998, Vol. 62, pages 1353-1360, especially pages 1355-1356 and Table 1.	1 and 2
X	FANG et al. The spectrum of mutations in UBE3A causing Angelman syndrome. Human Molecular Genetics. 1999, Vol. 8, No. 1, pages 129-135, especially pages 133-134.	1 and 2
X	MONCLA et al. Phenotype-genotype correlation in 20 deletion and 20 non-deletion Angelman syndrome patients. European Journal of Human Genetics. 1997, Vol. 7, pages 131-139, especially pages 131-132.	1 and 2
X	VEENSTRA-VANDERWEELE et al. Mutation screening of the UBE3A/E6-AP gene in autistic disorder. Molecular Psychiatry. 1999, Vol. 4, pages 64-67, especially page 66.	1 and 2

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
27 September 2001 (27.09.2001)

Date of mailing of the international search report
16 NOV 2001

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Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/17994

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	NCBI Database for Single Nucleotide Polymorphisms. National Center for Biotechnology Information, National Library of Medicine, NIH (Bethesda, MD, USA). Variations for gene model (contig mRNA transcript) XM041141. 29 January 2001.	1 and 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/17994

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1 and 2, with respect to group 1

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Groups 1-15, claims 1 and 2, drawn to methods for haplotyping UBE3A comprising determining whether the individual has one of the haplotypes shown in the recited table. For example if Group 1 is elected, then claims 1 and 2 will be examined to the extent that they are limited to methods of haplotyping comprising a step of determining whether the individual has the first haplotype set forth in the recited table. Upon election of one of the groups, please specify the number of the haplotype requested.

Groups 16-30, claims 3 and 4, drawn to methods for haplotyping UBE3A comprising determining whether the individual has one of the haplotype pairs shown in the recited table. For example if Group 16 is elected, then claims 3 and 4 will be examined to the extent that they are limited to methods of haplotyping comprising a step of determining whether the individual has the first haplotype pair forth in the recited table. Upon election of one of the groups, please specify the number of the haplotype pair requested.

Groups 31-44, claims 5-10, drawn to a method for genotyping the UBE3A gene. It is noted that Groups 31-44 correspond to polymorphic sites PS1, 2, 3, 4, etc, respectively. For example, if Group 31 is elected, then claims 5-10 will be examined to the extent that they apply are limited to method of genotyping comprising a step of identifying the nucleotide pair at PS1.

Groups 45-164, claims 11-12, drawn to a method for predicting a haplotype pair for theUBE3A gene by identifying a UBE3A genotype for the individual at two or more polymorphic sites. It is noted that the claims encompass methods requiring identification of 120 possible combinations of two of the recited polymorphic sites, and that Groups 45-164 each correspond to one of these possible pairs, in the order recited in the claim. For example, if Group 45 is elected, then claims 11-12 will be examined to the extent that they apply to a combination of PS1 and PS2. If applicants elect any of these groups, please specify the two sites to be examined in the method for predicting a haplotype.

Groups 165-194, claims 13-14, drawn to a method for identifying an association between a trait and a haplotype between one of the haplotypes or haplotype pairs of the UBE3A gene. Groups 165-194 each correspond to one of the particular combinations of the polymorphic sites, haplotypes and haplotype pairs encompassed by the claims. For example if Group 165 is elected, the claims will be examined to the extent that they apply to the first haplotype recited in the table.

Groups 195-208, claims 15-19, drawn to a composition comprising at least one genotyping oligonucleotide for detecting a polymorphism in the UBE3A gene.

Group 209, claims 20 and 21, drawn to a kit comprising a set of oligonucleotides designed to genotype each of the stated polymorphic sites of the UBE3A gene.

Groups 210-223, claims 22, 23, 26, 27, drawn to a polynucleotide which is a polymorphic variant of a reference sequence for UBE3A gene or a fragment thereof.

Groups 224-237, claims 24, 25, 28, 29, drawn to a recombinant nonhuman organisms comprising one of the recited haplotypes. For example, if Group 224 is elected the transgenic organism will be examined to the extent that it applies to haplotype 1.

Groups 238-267, claim 30, drawn to a computer system comprising polymorphism data wherein the data comprises the haplotypes and haplotype pairs set forth in the recited tables. For example, if Group 34 is selected, the computer system will be examined to the extent that it applies to the first haplotype of the recited table.

Groups 268-282, claim 31, drawn to a genome anthology comprising RRAS isogenes having any one of the haplotypes set forth in the recited table. It is noted that Groups 268-282 correspond to anthologies comprising one of the haplotypes 1-3 of the recited table. The inventions listed as Groups 1-282 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The products claimed in claims 15-19, 20-21, 22, 23, 26 and 27 include fragments of variant sequences, and the claims do not require, e.g., that the recited polymorphic sites be included in said fragments. Accordingly, the claims are sufficiently broad so as to encompass nucleic acid fragments taught in the prior art of (Yamamoto et al. National Center for Biotechnology Information. National Library of Medicine, NIH (Bethesda, MD, USA) GenBank Accession No. X98031, 29 April 1997). As the products of Groups 195-20-8, 209 and 210-223 do not represent a contribution over the prior art, the claims lack a special technical feature that is the same as or that corresponds to a special technical feature of the other claimed inventions. Thus, there is no special technical feature linking the recited Groups, as would be necessary to fulfil the requirement for unity of invention.

It is also noted that each of the present claims has been presented in improper Markush format, as distinct products and distinct methods are improperly joined in the claims. With respect to claims 15-19, 20, 21, 22, 23, 26 and 27, each polymorphic site and each molecule containing said polymorphic site is structurally and functionally distinct from and has a different special technical feature than each other polymorphic site and molecules containing said site. The chemical structure of each polymorphism and of each molecule containing the same differ from each other. For example, a polynucleotide comprising PS1 is chemically, structurally, and functionally different from a molecule comprising PS2. As the products and methods encompassed by the claims do not share a special technical feature, the distinct products and methods may not properly be presented in the alternative. Accordingly, the claims have been separated into a number of groups corresponding to the number of different inventions encompassed by the claims, and the claims will be examined only as they read upon the invention of the elected group. For the same reasons, the remainder of the claims have been separated in a number of groups corresponding to the number of different inventions encompassed thereby.

With particular respect to claims 5-10, claims 11-12, and claims 13-14, it is noted that the haplotypes and genotypes encompassed by these claims are also distinct from each other and from the single polymorphisms recited in e.g., claims 1-2. For example, a molecule of haplotype 1, comprising a particular combination of polymorphisms, differs chemically, structurally, and functionally from a molecule of haplotype 2 and from a molecule comprising a single polymorphism (e.g., PS1). The special technical feature of each haplotype or genotype is the combination of polymorphisms contained therein, which feature is lacking from and not shared with each other haplotype or genotype or with, e.g., a molecule comprising any single polymorphism set forth in the claims. Similarly, with respect to the pairs of polymorphisms, each combination of polymorphism differs from each other combination and from each of the other combinations discussed above (i.e., haplotypes, genotypes, and single polymorphic sites). Thus, the claims have been separated into a number of groups corresponding to the number of different inventions encompassed thereby, and the claims will be examined only as they read upon the invention of the elected group.

Further, Groups 195-108, 209, 210-223 (polynucleotides, kits, and various compositions), Groups 224-237 (recombinant organisms), Groups 238-267 (computer system) and Groups 268-282 (genome anthologies) are additionally drawn to multiple, distinct products lacking the same or corresponding special technical features. The nucleic acids are composed of nucleotides and function in, e.g., methods of nucleic acid hybridization or amplification. These groups are directed to different combinations of nucleic acids which are different from one another and may be employed in different methods. The recombinant organisms are complex organisms that are employed in, e.g. animal research methods. Such organisms cannot be employed as, e.g., probes or primers and they differ in both structure and function from the nucleic acids of Groups 224-237. Further the computer systems are composed of, e.g., a CPU, a display device, an input device, etc. and function in, e.g., methods of electronic sequence comparison. The genome anthologies of groups 268-282 are structurally and functionally distinct from the polynucleotides and computers. As products of different sets of Groups differ from each other in structure, function, and effect, they do not belong to a recognized class of chemical compound, or have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature".

Further, the methods of Groups 1-15, 16-30, 31-44, 45-164 and 165-194 have different objectives and require different process steps. The methods of Groups 1-15 and 16-30 require steps of identifying haplotypes and haplotype pairs to achieve the objectives of haplotyping. The methods of Groups 31-44 require steps of identifying a single nucleotide on one gene copy to achieve the objective of genotyping. The methods of 45-164 require steps of identifying two polymorphisms in a gene to achieve the objective of "predicting a haplotype pair". The methods of 165-194 requires steps of comparing frequencies of haplotypes in a population to achieve the objective of "identifying an association between a trait" and a haplotype. In addition to differences in objectives, effects, and method steps, it is again noted that the claims of the present Groups are not directed to the detection or identification of molecules having the same or common special technical feature, for the reasons discussed above.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/17994

Continuation of B. FIELDS SEARCHED Item 3:
DIALOG: Medline, CA, Biosis, EMBASE, SciSearch; WEST: US, EP, JP, WO Patents
search terms: UBE3A, smurf2, E6-AP, E6AP, E3-ubiquitin ligase, E6-associated protein, mutation, polymorphism, allele, variant, genotype, haplotype

10A_3_H1 DT / /02 100ng/ul	10A_3_H1 DT / /02 100ng/ul	10A_3_H1 DT / /02 100ng/ul	10A_3_H1 DT / /02 100ng/ul	10A_3_H1 DT / /02 100ng/ul
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7B_3_H1 DT / /02 100ng/ul	7B_3_H1 DT / /02 100ng/ul	8A_3_H1 DT / /02 100ng/ul	8A_3_H1 DT / /02 100ng/ul	8A_3_H1 DT / /02 100ng/ul
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9B_3_H1 DT / /02 100ng/ul	9B_3_H1 DT / /02 100ng/ul	9B_3_H1 DT / /02 100ng/ul	9B_3_H1 DT / /02 100ng/ul	

STACK	1	2	3	4	5	6	7	8	9	10	11	12	13
BOX													
A	Fusion 1	Fusion 6	Fusion 11	Fusion 16	Fusion 21	Fusion 26	Fusion 31	Fusion 115					
B	Fusion 2	Fusion 7	Fusion 12	Fusion 17	Fusion 22	Fusion 27	Fusion 32	Fusion 116					
C	Fusion 3	Fusion 8	Fusion 13	Fusion 18	Fusion 23	Fusion 28	Fusion 33	Fusion 117					
D	Fusion 4	Fusion 9	Fusion 14	Fusion 19	Fusion 24	Fusion 29	Fusion 101+102	Fusion 124					
E	Fusion 5	Fusion 10	Fusion 15	Fusion 20	Fusion 25	Fusion 30	Fusion 114	Fusion 125					

STACK	14	15	16	17	18	19	20	21	22	23	24	25	26
BOX													
A												A 23	CPD 01 - 10
B													CPD 21 - 25
C													CPD 11 - 21
D													Affy 40 cells
E													Affy 40 cells

Records for Media & Buffer Making

December, 2001

	1	2	2	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Total
0.8% TBE Agarose (1L)						11				16		5	15					15			15							15				92
1% TBE Agarose (200ml)										8																						8
2% TBE Agarose (200ml)																																0
1X TBE (1L)										20		10	18					20			20							15				103
1% Triton X 100 (1L)											2								4													6
MES 0.01%TritonX100 (1L)																																0
6XSSPE&0.01%Triton (1L)												20					20									20						60
4XSSPE&0.01%Triton (1L)											20							20		20							20					80
12X MES stock buffer (1L)																																0
1X MES buffer (1L)																																0
Hyb solution																																0
Notes																																

Records for Media & Buffer Making

December, 2001

	1	2	2	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Total
0.8% TBE Agarose (1L)						11				16		5	15					15			15							15				92
1% TBE Agarose (200ml)										8																						8
2% TBE Agarose (200ml)																																0
1X TBE (1L)										20		10	18					20			20							15				103
1% Triton X 100 (1L)											2								4													6
MES 0.01%TritonX100 (1L)																																0
6XSSPE&0.01%Triton (1L)												20					20									20						60
4XSSPE&0.01%Triton (1L)											20							20		20							20					80
12X MES stock buffer (1L)																																0
1X MES buffer (1L)																																0
Hyb solution																																0
Notes																																

STACK	1	2	3	4	5	6	7	8	9	10	11	12	13
BOX													
A	Fusion 1	Fusion 6	Fusion 11	Fusion 16	Fusion 21	Fusion 26	Fusion 31	Fusion 115					
B	Fusion 2	Fusion 7	Fusion 12	Fusion 17	Fusion 22	Fusion 27	Fusion 32	Fusion 116					
C	Fusion 3	Fusion 8	Fusion 13	Fusion 18	Fusion 23	Fusion 28	Fusion 33	Fusion 117					
D	Fusion 4	Fusion 9	Fusion 14	Fusion 19	Fusion 24	Fusion 29	Fusion 101+102	Fusion 124					
E	Fusion 5	Fusion 10	Fusion 15	Fusion 20	Fusion 25	Fusion 30	Fusion 114	Fusion 125					

STACK	14	15	16	17	18	19	20	21	22	23	24	25	26
BOX													
A												A 23	CPD 01 - 10
B													CPD 21 - 25
C													CPD 11 - 21
D													Affy 40 cells
E													Affy 40 cells

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Sausker, Elizabeth Ann

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<212> DNA
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<212> PRT
<213> Homo sapiens

<400> 8

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20 25 30

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35 40 45

Ala Leu Glu Leu Tyr Lys Ile Asn Ala Lys Leu Cys Asp Pro His Pro
50 55 60

Ser Lys Lys Gly Ala Ser Ser Ala Tyr Leu Glu Asn Ser Lys Gly Ala
65 70 75 80

Pro Asn Asn Ser Cys Ser Glu Ile Lys Met Asn Lys Lys Gly Ala Arg
85 90 95

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Val Ser Val Asp Ile Asp Ala Ile Arg Arg Val Tyr Thr Arg Leu Leu
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Ser Asn Glu Lys Ile Glu Thr Ala Phe Leu Asn Ala Leu Val Tyr Leu
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Ser Pro Asn Val Glu Cys Asp Leu Thr Tyr His Asn Val Tyr Ser Arg
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Asp Pro Asn Tyr Leu Asn Leu Phe Ile Ile Val Met Glu Asn Arg Asn
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Leu His Ser Pro Glu Tyr Leu Glu Met Ala Leu Pro Leu Phe Cys Lys
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Ala Met Ser Lys Leu Pro Leu Ala Ala Gln Gly Lys Leu Ile Arg Leu
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Trp Ser Lys Tyr Asn Ala Asp Gln Ile Arg Arg Met Met Glu Thr Phe
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Gln Gln Leu Ile Thr Tyr Lys Val Ile Ser Asn Glu Phe Asn Ser Arg
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Asn Leu Val Asn Asp Asp Asp Ala Ile Val Ala Ala Ser Lys Cys Leu
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Thr Leu Gln Glu Leu Leu Gly Glu Glu Arg Arg Asn Lys Lys Gly Pro
385                 390                 395                 400

Arg Val Asp Pro Leu Glu Thr Glu Leu Gly Val Lys Thr Leu Asp Cys
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Arg Lys Pro Leu Ile Pro Phe Glu Glu Phe Ile Asn Glu Pro Leu Asn
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Glu Val Leu Glu Met Asp Lys Asp Tyr Thr Phe Phe Lys Val Glu Thr
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Glu Asn Lys Phe Ser Phe Met Thr Cys Pro Phe Ile Leu Asn Ala Val
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Thr Lys Asn Leu Gly Leu Tyr Tyr Asp Asn Arg Ile Arg Met Tyr Ser
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Glu Arg Arg Ile Thr Val Leu Tyr Ser Leu Val Gln Gly Gln Gln Leu
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Asn Pro Tyr Leu Arg Leu Lys Val Arg Arg Asp His Ile Ile Asp Asp
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Ala Leu Val Arg Leu Glu Met Ile Ala Met Glu Asn Pro Ala Asp Leu
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Lys Lys Gln Leu Tyr Val Glu Phe Glu Gly Glu Gln Gly Val Asp Glu
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Gly Gly Val Ser Lys Glu Phe Phe Gln Leu Val Val Glu Glu Ile Phe
545                 550                 555                 560

Asn Pro Asp Ile Gly Met Phe Thr Tyr Asp Glu Ser Thr Lys Leu Phe
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Trp Phe Asn Pro Ser Ser Phe Glu Thr Glu Gly Gln Phe Thr Leu Ile
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Gly Ile Val Leu Gly Leu Ala Ile Tyr Asn Asn Cys Ile Leu Asp Val
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Phe Gln Ile Ser Gln Thr Asp Leu Phe Gly Asn Pro Met Met Tyr Asp
660 665 670

Leu Lys Glu Asn Gly Asp Lys Ile Pro Ile Thr Asn Glu Asn Arg Lys
675 680 685

Glu Phe Val Asn Leu Tyr Ser Asp Tyr Ile Leu Asn Lys Ser Val Glu
690 695 700

Lys Gln Phe Lys Ala Phe Arg Arg Gly Phe His Met Val Thr Asn Glu
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Ser Pro Leu Lys Tyr Leu Phe Arg Pro Glu Glu Ile Glu Leu Leu Ile
725 730 735

Cys Gly Ser Arg Asn Leu Asp Phe Gln Ala Leu Glu Glu Thr Thr Glu
740 745 750

Tyr Asp Gly Gly Tyr Thr Arg Asp Ser Val Leu Ile Arg Glu Phe Trp
755 760 765

Glu Ile Val His Ser Phe Thr Asp Glu Gln Lys Arg Leu Phe Leu Gln
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Phe Thr Thr Gly Thr Asp Arg Ala Pro Val Gly Gly Leu Gly Lys Leu
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Ser His Thr Cys Phe Asn Val Leu Leu Leu Pro Glu Tyr Ser Ser Lys
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